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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,284	01/02/2002	Masako Izui	217677US0PCT	1454
22850	7590	10/06/2003	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.			SLOBODYANSKY, ELIZABETH	
1940 DUKE STREET			ART UNIT	PAPER NUMBER
ALEXANDRIA, VA 22314			1652	

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/019,284

Applicant(s)

IZUI ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,6,16.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

This application is a 371 of PCT/JP00/04348 filed June 30, 2000.

Claims 1-3 are pending.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Objections***

Claims 1-3 are objected to because of the following informalities: claims 1 and 2 recite (A), (B) while claim 3 recites (a), (b). It is suggested that applicants maintain consistency through out the application and refer to "(a), (b)". Further, reference to "in the Sequence Listing" is redundant and should be deleted.

Furthermore, the proper recitation of Markush group is a protein or DNA "selected from the group consisting of (a) and (b).

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1(B) is drawn to a protein having an amino acid sequence of SEQ ID NO: 2 including substitution, deletion, insertion, addition or inversion of one or several amino acids and activity for binding sucrose. Claim 2(B) is drawn to a DNA encoding said protein. Claim 3(b) is drawn to a DNA which is hybridizable with a nucleotide sequence of the nucleotides 3779-5761 of SEQ ID NO:1 and having an activity for binding sucrose. Since the number of allowed mutations in claims 1-2 is not limited in terms of the mutant's sequence homology to SEQ ID NO:2 and the hybridization conditions are not defined in claim 3, claims 1-3 encompass a protein of any structure having an activity of binding to sucrose and a DNA encoding thereof.

The specification does not contain any disclosure of the structures of all proteins that bind sucrose or DNAs encoding thereof. The genus of proteins that comprise these molecules is a large variable genus comprising many structurally diverse proteins. Furthermore, these proteins are functionally diverse as well because proteins with different activities may bind sucrose. The specification discloses only a single species of the claimed genus, an enzyme II of the phosphotransferase system (PTS II) from

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*Brevibacterium lactofermentum* having the amino acid sequence of SEQ ID NO:2 that is encoded by nucleotides 3779-5761 of SEQ ID NO:1. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the "functionality" of binding sucrose and fails to provide any structure: function correlation present in all members of the claimed genus. Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein of SEQ ID NO:2 and a DNA of SEQ ID NO:1, does not reasonably provide enablement for a protein that binds sucrose having an unknown homology to SEQ ID NO:2 and a DNA having an unknown homology to SEQ ID NO:1 and encoding a protein that binds sucrose. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of

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direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Factors pertinent to this discussion include predictability of the art, guidance in the specification, breadth of claims, and the amount of experimentation that would be necessary to use the invention.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins of different strictures and functions that bind sucrose and DNAs encoding thereof.

The specification teaches DNA of SEQ ID NO:1 that encodes an enzyme II of the phosphotransferase system (PTS II) from *Brevibacterium lactofermentum* having the amino acid sequence of SEQ ID NO:2 that is encoded by nucleotides 3779-5761 of SEQ ID NO:1. The specification does not teach any PTS II enzymes or other proteins that bind sucrose and comprise mutations in SEQ ID NO:2 and DNAs encoding thereof. Further, it fails to provide information regarding other combinations of substitute amino acids that would result in a mutant with the requisite characteristics. While there is a great number of possible mutants, it is *a priori* unpredictable as to which mutant will

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exhibit the claimed property. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The amino acid sequence of a protein determines its structural and functional properties, and predictability of what changes in the amino acid sequence can be tolerated and result in similar activity is extremely complex, and well outside the realm of routine experimentation, because accurate predictions of a protein's structure from mere sequence data are limited. Furthermore, while recombinant techniques are available, it is not routine in the art to screen large numbers of peptide mutants where the expectation of obtaining similar activity is unpredictable based on the instant disclosure.

The specification does not support the broad scope of the claims which encompass any PTS II enzyme or any protei that binds sucrose and a DNA encoding thereof because the specification does not establish: (A) regions of the protein structure which may be modified without effecting the requisite activity; (B) the general tolerance of PTS II enzyme to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any PTS II enzyme residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

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Therefore, one of ordinary skill would require guidance, such as information regarding the specific amino acid changes that would render a PTS II enzyme or any other protein activity to bind sucrose, in order to make a PTS II or any protein that binds sucrose having amino acid and nucleotide sequences other than SEQ ID NO:1 and 2 in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 recite "inversion". The term is unclear in relation to an amino acid. Claim 3 recites "a DNA which is hybridizable". Without knowing the hybridization conditions, it is impossible to know DNAs of which structures hybridize. Furthermore, "hybridizable" relates to a latent ability. Amending the claim to recite "a DNA which hybridizes" with indication of the specific conditions is suggested.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:



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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

the claimed invention is directed to non-statutory subject matter. Protein of SEQ ID NO:2 and DNA of SEQ ID NO:1 naturally occur in *Brevibacterium lactofermentum*.

As the products of Nature, they are unpatentable. Amending the claims to recite, for example, "an isolated" product is suggested.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner

et al.

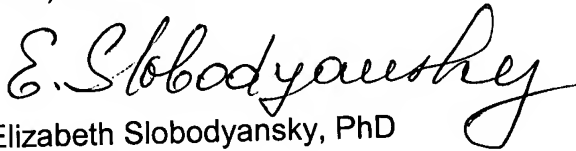
Wagner et al. (form PTO-1449 filed January 2, 2002) teach the *scrA* gene encoding the sucrose-specific enzyme II of the phosphotransferase system from *Staphylococcus xylosus*. The protein taught by Wagner et al binds sucrose. As explained above, claim 1(b) limits a protein by an activity to bind sucrose only not by the structure. Therefore, the sucrose-specific enzyme II and a DNA encoding thereof taught by Wagner et al anticipate claims 1-3.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD  
Primary Examiner

September 30, 2003